Administering Drug Programs: Protecting Consumers' Interests

States are increasingly turning to third parties, specifically Pharmacy Benefit Managers (PBMs), to administer their Medicaid drug benefit, pharmacy assistance, discount, or other prescription drug programs. Whether your state is considering using a PBM for a new program or switching to PBM management for an existing program, some steps should be taken to make sure that the PBM does not have conflicts of interest that might diminish consumers' access to appropriate therapies.[1]

If the state considers contracting with a Pharmacy Benefit Manager (PBM)

Most PBMs have relationships with pharmaceutical companies. Some of these relationships pose conflicts of interest; they create incentives that would reduce program savings or, at worst, harm consumers. Before entering into any agreement with a PBM, it is important to know about any relationships it has with pharmaceutical companies and to understand how those might affect its ability to administer the program.

In selecting a PBM, work with the state to try to find a PBM that does not have any relationships that would pose conflicts. If that is not possible, make sure that the state program is exempted from any PBM arrangements that might pose conflicts. Program oversight, as described below, will be critical to ensuring that consumers' interests are protected on an ongoing basis.

- **As a condition of contracting, require the PBM to disclose relationships with pharmaceutical companies.** The PBM might have relationships with pharmaceutical companies that could color the way it administers the program, such as agreements to favor certain manufacturers' drugs, agreements to share revenue with mail order or internet companies, or rebate-sharing agreements with pharmaceutical companies.
- **If the PBM has rebate agreements, make sure that rebates will be shared with consumers.** PBMs have agreements to receive rebates from pharmaceutical manufacturers. Unless required to do so by contract, PBMs may retain all or part of those rebates. Require that rebates be passed on to the program, either to defray costs in the case of subsidy programs or, in the case of discount programs, to make larger price reductions available to consumers.

- **Require the PBM to disclose data-sharing agreements**. PBMs often have agreements to share physician prescribing data with pharmaceutical companies. Those companies may use that data for marketing purposes. Make sure that the state requires the PBM to disclose any arrangements that it has to share data, such as physician prescribing or utilization data, and try to exempt the state program from all data-sharing arrangements.

Program administration issues with or without a PBM relationship

Whether the state opts for PBM management or manages the program itself, you should make sure that any cost-containment strategies used are structured so that they improve the quality of patient care.

- **Have oversight by a Pharmacy and Therapeutics Committee.** Cost-containment strategies should be developed and overseen by a Pharmacy and Therapeutics Committee (P&T) that includes independent physicians and pharmacists. Consumers should have input in P&T membership selection.
- **Provide for consumer input, public hearings.** A board should oversee program management. That board should include consumer representation. Board meetings should be open to the public and all meeting minutes and other documents should be available as public records.
- **Include an appeals process.** If the program uses formularies, prior authorization, or other administrative mechanisms to control costs, consumers should be able to appeal decisions that limit their access to prescribed drugs. In cases where copayments differ for generic, preferred brand, and off-formulary drugs, the appeals process should include mechanisms that allow individuals to pay a lower copayment if taking the higher-copayment drug is medically necessary. The appeals process should require prompt review and consumer notification.

[1] Pharmacists' groups are beginning to push states for greater regulation of PBMs. Information on pharmacists' activities can be found through the Web site for the National Community Pharmacists Association at (http://www.ncpanet.org/).

Guidelines for Monitoring Common PBM Strategies to Contain Pharmacy Costs

A variety of clinical and administrative strategies can be used to contain pharmacy costs. These strategies, which are relevant primarily for Medicaid and subsidy programs that are PBM-managed, are commonly used by PBMs. If properly managed, some of these activities can support proper prescribing and reduce program costs. The potential does exist, however, for these approaches to control operating costs at the expense of patient care. An independent board that includes physicians and consumers should monitor program management, should decide which of the strategies outlined below will be used and under what circumstances, and which will be managed at the pharmacy and which through the physician.

The commonly used strategies discussed below are defined in the *Glossary of Terms* in this kit.

- **Formularies.** Formularies can effectively promote use of generics, which can reduce costs without compromising care. However, they must include at least one drug from all therapeutic classes. Make sure that PBM formularies favor generics, not brands from manufacturers that give the PBM the largest rebate. Make sure that, if considered medically necessary by the patient's physician, patients can be prescribed drugs not on the formulary or from a different formulary "tier" (higher copayment) without a financial penalty.
- **Drug Utilization Review.** DUR programs can be used prospectively to alert pharmacists when a patient might be taking drugs that could adversely interact, which is appropriate, or retrospectively to review physician prescribing. Retrospective review can be appropriate if used to educate physicians regarding use of generics; however, it can be inappropriately used to direct physicians to specific brands preferred by the PBM. The way the program will use DUR should be defined and carefully managed by the program's independent P&T Committee.
- **Guidelines and Drug Treatment Protocols.** Guidelines can promote more cost-effective, logical care. However, they should be developed by physicians, focus on quality of care, allow for exceptions, and reflect generally accepted treatment in the community. Guidelines and drug treatment protocols should be reviewed by the program's independent P&T Committee.
- **Therapeutic Substitution.** If the program uses therapeutic substitution, a process should be in place to quickly switch consumers to the originally prescribed compound at no cost to the consumer if the physician requests the change (e.g., the substitute does not work as well).
- **Prior Authorization.** If not properly managed or if used on most rather than a very few therapies, prior authorization can hinder access, and the added administrative costs can outweigh any potential benefit. Any prior-authorization system should require a prompt decision, include appeals processes, and have exceptions for emergencies.